K080859

JUN - 4 2008

510 (k) Summary

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter:
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Date Prepared:
March 14, 2008

Trade Name:
DRF 4343

Common Name:
Operator Console and Imaging Workstation for Stationary Digital X-Ray Systems

Classification Name:
892.1630 Solid State x-ray imaging system

Predicate Devices:
The DRF 4343 is compared with the following predicate devices:

- Nical NDR+/DIVA-D (K053029),
- Siemens AXIOM Luminos dRF (K062623),
- Shimadzu DAR7000 RADspeed SAFIRE (K050925).

Product Description:
The DRF 4343 is intended to capture digital images from a radiographic/fluoroscopic system through a dynamic digital flat panel, to digitalize, archive and review images and to provide a network connection via DICOM protocol to various output (e.g. hardcopy, softcopy and archive) devices which uses a device.

Indication for Use:
The DRF 4343 is a digital image acquisition system to be used in conjunction with a solid-state detector during radiography or fluoroscopy x-ray examination to capture, digitalize, review images and format images according to DICOM protocol to be sent through network connection.

This device is not intended for mammography use.

Rationale for Substantial Equivalence:
The DRF 4343 has the same indication for use as the predicate devices. It shares the same technological characteristics as the predicate devices. Minor technological differences do not raise any new questions regarding safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Paolo Casagrande Santin
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BUCCINASCO (MI) 20090
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AUG - 9 2013

Re: K080859
Trade/Device Name: DRF 4343
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified Fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA and MQB
Dated: March 25, 2008
Received: March 28, 2008

Dear Mr. Santin:

This letter corrects our substantially equivalent letter of June 4, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use Statement

510k Number: (if known): _____

Device Name: DRF 4343

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(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K080859